

Preliminary Amendment

National Stage Entry of PCT/AU2003/001250
Attorney Docket No.: Q86490

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (original): A process for the production of a vaccine composition of labile immunogens, wherein a fluid comprising one or more immunogens is sprayed into a reactor containing fluidized particles of a pharmaceutically acceptable water soluble material at a temperature of about 25°C to about 50°C, such that the immunogen coats and is dried onto the particles under the fluidizing conditions, and thereafter collecting from said reactor dried immunogen containing particles having a moisture content between about 0.1% w/w to about 10% w/w so as to give a stabilized vaccine composition.

2. (original): A process according to claim 1 wherein the immunogen comprises virus particles, bacterial cells or other microorganisms, or antigenic products thereof.

3. (original): A process according to claim 2 wherein the immunogen comprises virus particles or bacterial cells.

4. (original): A process according to claim 2 wherein the immunogen comprises a viral or bacterially derived immunogen selected from a protein, peptide, glycoprotein, or glycolipid, or polysaccharide, optionally associated with a carrier, which on immunization of a subject provokes an immune response to the virus or bacteria from which the immunogen was derived.

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5. (original): A process according to claim 1 wherein the fluid comprising one or more immunogens is a viral vaccine or bacterial vaccine preparation mixed with a stabilising diluent to provide a fluid comprising viral particles or bacterial immunogens.

6. (original): A process according to claim 1 wherein the temperature is from about 30°C to about 46°C.

7. (original): A process according to claim 1 wherein the moisture content is from 0.1% w/w to 2.6% w/w.

8. (original): A process according to claim 7 wherein the moisture content is from 0.2% w/w to 1.5% w/w.

9. (currently amended): A process according to ~~any one of claims 1 to 8~~ claim 1 wherein said fluid comprising one or more immunogens is a suspension or dispersion of immunogens selected from viral particles, bacterial cells or other microorganisms, eukaryotic cells, or antigenic products of said immunogens.

10. (currently amended): A process according to ~~any one of claims 1 to 9~~ claim 1 wherein said fluid containing one or more immunogens includes one or more amino acids, proteins, chelating agents, buffers, preservatives, stabilizers, mineral salts, metal antioxidants, lubricants and adjuvants.

11. (original): A process according to claim 9 wherein viral particles or bacterial cells in a culture medium, vaccine composition or other fluid are diluted with a diluent.

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12. (original): A process according to claim 1 wherein said particles of a pharmaceutically acceptable water soluble material comprise one or more monosaccharide, disaccharide, polysaccharide, carbohydrate, water soluble peptide, mineral salt, water soluble polymer, or water soluble pharmaceutically acceptable excipient.

13. (currently amended): A process according to ~~any one of claims 1 to 12~~ claim 1 wherein said pharmaceutically acceptable water soluble material comprises one or more sugars.

14. (currently amended): A process according to ~~any of claims 1 to 13~~ claim 1 wherein the pharmaceutically acceptable water soluble material comprises a particle size from 20 microns to 1 mm.

15. (original): A process according to claim 14 wherein said particle size is from 50 microns to 200 microns.

16. (currently amended): A process according to ~~any of claims 1 to 15~~ claim 1 wherein said reactor is a spray drying reactor of fluidized bed into which immunogen containing fluid is sprayed onto fluidized particles and dried thereon.

17. (original): A process according to claim 16 wherein fluid comprising one or more immunogens is sprayed through a nozzle or spray head which delivers the sprayed fluid into the reactor.

18. (original): A process according to claim 16 wherein said particles are fluidized in a reactor containing a fluidized bed at a rate between 200 to 500 m²/h.

19. (original): A process according to claim 1 wherein said stabilized vaccine composition is stable and efficacious on storage at 25°C for 30 days.

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20. (original): A process according to claim 1 wherein the vaccine composition is a free flowing particulate material.

21. (currently amended): A process according to ~~any of claims 1 to 20~~ claim 1 which further comprises mixing together two or more free flowing stabilized vaccine compositions containing different immunogens to give a multivalent vaccine composition.

22. (original): A process according to claim 3 wherein said virus particles or bacteria is a carrier for the delivery of DNA sequences, RNA sequences or vaccine antigens.

23. (original): A process according to claim 3 wherein said virus particles or bacteria are genetically modified.

24. (original): A stabilized vaccine composition comprising immunogen coated particles of a pharmaceutically acceptable water soluble material, the composition having a moisture content between about 0.1% w/w to about 10% w/w.

25. (original): A vaccine composition according to claim 24 wherein the immunogen comprises virus particles, bacterial cells or other microorganisms or antigenic products thereof.

26. (original): A vaccine composition according to claim 24 wherein the immunogen comprises virus particles or bacterial cells.

27. (original): A vaccine composition according to claim 26 which contains live virus particles capable of reproduction in an immunized host.

28. (original): A vaccine composition according to claim 24 wherein the immunogen comprises a viral or bacterially derived immunogen selected from a protein, peptide, glycoprotein, or glycolipid, or polysaccharide, optionally associated with a carrier, which on

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immunization of a subject provokes an immune response to the virus or bacteria from which the immunogen was derived.

29. (currently amended): A vaccine composition according to ~~claims 24 to 28~~ claim 24 which is stable and efficacious on storage at 25°C for 30 days.

30. (currently amended): A vaccine composition according to ~~claims 24 to 29~~ claim 24 wherein the pharmaceutically acceptable water soluble material comprises one or more of a monosaccharide, disaccharide, polysaccharide or carbohydrate, water soluble peptide or peptides, gelatine, mineral salt or water soluble polymer, or water soluble pharmaceutically acceptable excipient.

31. (original): A vaccine composition according to claim 30 wherein said water soluble material comprises one or more sugars.

32. (original): A vaccine composition according to claim 24 comprising two or more different immunogen coated particles, so as to give a multivalent vaccine.

33. (currently amended): A vaccine composition according to ~~any of claims 24 to 32~~ claim 24 wherein the immunogen is a carrier of a nucleic acid sequence or a peptide or polypeptide.

34. (currently amended): A vaccine composition according to ~~any of claims 24 to 33~~ claim 24 which comprises a particle size from 50 microns to 400 microns.

35. (original): A process according to claim 34 wherein said particle size is from 50 microns to 200 microns.

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36. (currently amended): A composition according to ~~any of claims 24 to 35~~ claim 24 wherein said immunogen coated particles include one or more amino acids, proteins, chelating agents, buffers, preservatives, stabilizers, mineral salts, antioxidants, lubricants and adjuvants.

37. (original): A vaccine composition according to claim 24 which is a free flowing particulate composition.

38. (currently amended): A vaccine composition according to ~~claims 24 to 37~~ claim 24 which is immunogenic on administration to an animal or human.

39. (currently amended): A vaccine composition according to ~~claims 24 to 37~~ claim 24 which is a human or animal vaccine.

40. (original): A vaccine according to claim 39 which is a poultry vaccine for the prevention of Newcastle Disease, infectious bronchitis, coccidiosis, fowl pox, fowl cholera, reovirus induced tenosynovitis (viral arthritis), fowl laryngotracheitis, avian encephalomyelitis, infectious bursal disease (IBD), Marek's Disease, salmonella infection, mycoplasma gallisepticum infection, avian rhinotracheitis, avian herpes and Mycoplasma hyponeumoniae, Egg Drop Syndrome, Infectious Coryza (Haemophilis pasagallinarum), mycoplasma synoviae or avian reovirus.

41. (original): A vaccine composition according to claim 39 is a porcine vaccine, for the prevention or treatment of *Actinobacillus pleuropneumoniae*, atrophic rhinitis, pseudorabies, swine erysipelas, porcine parvovirus, *E-coli* enterotoxicosis, myoplasma hyopneumoniae, influenza, leptospira, *E.-coli* infection, Porcine Reproductive and Respiratory Syndrome (PRRS), *Bordetella* and *multocida* types A and D infections, *haemophilus parasuis* infection, *clostridium*

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perfringens infection, rotavirus infection, *Streptococcus suis* infection, Glasser's Disease, pneumonia, *bordetella bronchiseptica* infection.

42. (original): A vaccine according to claim 39 which is a human vaccine for the prevention of influenza, hepatitis A, hepatitis B, hepatitis C, herpes simplex virus (type 2), polio, diphtheria, pertussis, *haemophilus influenza* type B (Hib), measles, mumps, rubella, typhoid fever, varicella (chicken pox), Dengue fever, Epstein-Barr virus infection, human papillomavirus infection, *Streptococcus pneumoniae* infection, *Neisseria meningitidis* infection, Pneumococcal infection, viral meningitis, rotavirus infection, tick-borne encephalitis, travel diarrhea, cholera, yellow fever or tuberculosis.